

Status of Pending Claims

Applicants note that claims 1, 2 and 4 to 7 are pending. Applicants note that the Examiner has indicated that claims 6 and 7 were allowed. Applicants note that the Examiner has indicated that claims 1, 2, 4 and 5 were rejected.

The Section 112, Second Paragraph Rejection of Claim 4

Claim 4 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly indefinite. In particular, the Examiner appears to object to the term "selectively" as indefinite.

This rejection is respectfully traversed. Applicants submit that, when considered in view of the teachings of the specification, Applicants' use of the term "selectively" in claim 4 clearly complies with the requirements of the second paragraph of Section 112.

Applicants note that the specification of the present application clearly provides a standard for ascertaining what is meant by the term "selectively" as it is used in claim 4. In particular, Applicants direct the Examiner's attention to the Specification at page 11, lines 14 to 22.

Applicants request that the Examiner reconsider this rejection and withdraw it.

The Section 112, First Paragraph Rejection

Claims 2 and 5 stand rejected under 35 U.S.C. §112, first paragraph, for lack of written description.

Applicants note that the Examiner appears to base the present rejection on the rationale that, because Applicants have not provided data in the application demonstrating that any specified compound has an  $IC_{50}$  for matriptase or MTSP1 of 100nM or less, they have not fulfilled the written description requirement.

Applicants submit that this rejection is not well taken. Applicants submit that they have complied with the written description requirement of the First Paragraph of Section 112. They have described the use of certain specific compounds for decreasing matriptase or MTSP1 activity and described an assay for determining those compounds which have an  $IC_{50}$  for matriptase or MTSP1 of 100nM or less. Applicants submit that such description clearly demonstrates that they were in possession of the claimed invention at the time the application was filed. *OK for enable.*

Accordingly, Applicants request that the Examiner reconsider this rejection and withdraw it.

#### The Section 102(b) Rejection

Claims 1 and 4 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,492,895 to Vlasuk et al ("Vlasuk et al"), United States Patent No. 5,696,231 to Abelman et al ("Abelman et al I") and U.S. Patent No. 5,776,027 to Abelman et al ("Abelman et al II").

This rejection is respectfully traversed. Applicants submit that claims 1 and 4 are clearly not anticipated by any of Vlasuk et al, Abelman et al I or Abelman et al II.

The Examiner appears to base this rejection on his erroneous assertion that claims 1 and 4 are directed to

compounds having structures identified by the cited references. Applicants note that the Examiner is mistaken in that claims 1 and 4 are not directed to compounds *per se*, but, instead, claims 1 and 4 are directed to methods of treatment by administering certain specified compounds. Applicants note that even if some of the specified compounds were described by the cited references, the claims are directed to a novel use of the specified compounds which is not taught by any of the references.

Applicants note that Vlasuk *et al*, Abelman *et al* I and Abelman *et al* II are directed to compounds which are described as inhibitors of certain enzymes in the coagulation cascade. In particular, Vlasuk *et al* are directed to compounds which have activity as inhibitors of thrombin and/or Factor Xa. Abelman *et al* I are directed to compounds which have activity as inhibitors of Factor Xa. Abelman *et al* II are directed to compounds which have activity as inhibitors of thrombin or Factor Xa.

Applicants note that it is axiomatic that in order to constitute an anticipation, a single reference must disclose all the elements of the claim that is allegedly anticipated.

None of the cited references describe Applicants' use as claimed in claims 1 and 4. Claims 1 and 4 are directed to new methods of therapy which involve inhibiting the enzyme matriptase of MTSP1. The references do not teach the use of any of the compounds they may disclose for the treatment of a condition which is ameliorated by inhibiting or decreasing serine protease activity of matriptase or MTSP1 by administering one of a specified group of matriptase or MTSP1 inhibitors as set forth in claims 1 and 4.

Even if, as asserted by the Examiner, the cited references describe certain of the specific compounds whose use is claimed by claims 1 or 4, the references fail to disclose the use of any of their compounds as a matriptase or MTSP1 inhibitor.

Accordingly, the cited references cannot anticipate a claim directed to a method of use if they fail to disclose the claimed use. Clearly, the rejection of claims 1 and 4 as anticipated by Vlasuk et al, Abelman et al I and/or Abelman et al II should not stand.

Applicants submit that the present rejection has been overcome and request that it be withdrawn.

#### CONCLUSION


In view of the foregoing, Applicants submit that all the rejections of claims 1, 2, 4 and 5 have been overcome and that those claims are allowable. Applicants note that the Examiner indicated that claims 6 and 7 were allowed. Applicants request that the claims be allowed and passed to issue.

If the Examiner believes that a telephonic interview would expedite allowance of this application, he is encouraged to telephone Applicants attorney of record, Suzanne L. Biggs at the below-noted telephone number.

The Commissioner is hereby authorized to charge any fee, including any fee due with this submission, if the request to change the deposit account is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its entire

pendency to or to credit any overpayment to Deposit Account 03-3975, Order No. 018813-0278799.

Respectfully submitted,  
PILLSBURY WINTHROP LLP

By   
Suzanne L. Biggs  
Registration No. 30,158

Dated: July 28, 2003

Attorney Docket No. 018813-0278799  
Address all correspondence to:  
11682 El Camino Real, Suite 200  
San Diego, CA 92130  
Tel: (858) 509-4095  
Fax: (858) 509-4010